UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,973	09/18/2003	Quang Tran	016355-004600US	5340

8791 7590 04/17/2007

BLAKELY SOKOLOFF TAYLOR & ZAFMAN
12400 WILSHIRE BOULEVARD
SEVENTH FLOOR
LOS ANGELES, CA 90025-1030

EXAMINER	
ALI, SHUMAYA B	
ART UNIT	**PAPER NUMBER**
3771	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

ED

Office Action Summary	Application No.	Applicant(s)	
	10/665,973	TRAN ET AL.	
	Examiner	Art Unit	
	Shumaya B. Ali	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/3/06,4/21/05,12/15/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-21, and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 17, the recitation of "between about 1.2 cm and about 2.0 cm" in line 2 is considered indefinite because what is considered "about 1.2 cm and about 2.0 cm" cannot be determined. As to claim 18, the recitation of "between about 1.6 cm and about 2.4 cm" in line 2, as to claim 21, the limitation of "between about 43 cm and about 50 cm" in line 2, and as to claim 27, the recitation of "between about 1.2 cm and about 2.0 cm" in line 4 is further considered indefinite for the reasons provided for claim 17.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6,8-22,26, and 27 are rejected under 35 U.S.C. 102 (b) as being anticipated by Giba et al. US 5,876,373.

As to claim 1, Giba discloses a catheter **(fig.1, 100)** for delivering a contraceptive device within a fallopian tube, the catheter comprising: an elongate tubular catheter body **(fig.1, 100)** having a proximal **(102)** portion adjacent a proximal end **(proximal end is toward the handle 102, see fig.1)**, a distal portion **(fig.1, 110)** adjacent a distal end **(distal end is toward the elongated tube 110, see fig.1)**, and at least one lumen **(fig.3 depicts that a lumen contains coil 130)**; and at least one coil **(figs.3 and 4, 130)** disposed along the catheter body nearer the distal end than the proximal end and encircling the lumen **(see fig.2)**.

As to claim 2, Giba discloses a catheter as in claim 1, wherein the distal portion of the catheter body is more flexible towards the distal end of the catheter body than towards the proximal end **(see col.8, lines 15 and 16).**

As to claim 3, Giba discloses a catheter as in claim 2, wherein the distal portion of the catheter body comprises multiple layers **(fig.3, 114,120, and 130,)**, and the at least one coil comprises one of the layers **(fig.3 depicts that 130 is a coil layer)**.

As to claim 4, Giba discloses a catheter as in claim 3, wherein the multiple layers comprise: an inner layer **(fig.3, 114)**; a middle layer **(fig.3, 130)**; and an outer layer **(fig.4, 120)**.

As to claim 5, Giba discloses a catheter as in claim 4, wherein the middle layer comprises the coil **(fig.3 depicts that the middle layer comprises the coil 130).**

As to claim 6, Giba discloses a catheter as in claim 5, wherein the coil comprises at least one material selected from the group consisting of Nitinol®, stainless steel, titanium and a polymer **(col.9, lines 63-67)**.

As to claim 7, Giba discloses a catheter as in claim 4, wherein the inner layer comprises at least one material selected from the group consisting of Teflon®, etched polytetraflouroethylene and a fluoropolymer **(col.9, lines 63-67)**.

As to claim 8, Giba discloses a catheter as in claim 4, wherein the outer layer comprises at least one polyurethane material **(col.9, lines 63-67)**.

As to claim 10, Giba discloses a catheter as in claim 2, wherein the distal portion comprises: a first segment **(fig.2, 162)**; and at least a second segment **(fig.12, 110)** distal to the first segment, wherein the second segment is more flexible than the first segment **(col.8, lines 15 and 16; and coil part 130 in the second segment makes the second segment more flexible than the first segment)**.

As to claim 11, Giba discloses a catheter as in claim 10, further comprising a third segment **(fig.2, 106)** distal to the second segment, wherein the third segment is more flexible than the second segment **(col.8, lines 15-17)**.

As to claim 12, Giba discloses a catheter as in claim 11, wherein the distal portion comprises: an inner layer **(fig.3, 114)**; a middle layer **(fig.3, 130)**; and an outer layer **(fig.3, 120)**.

As to claim 13, Giba discloses a catheter as in claim 12, wherein the middle layer comprises the coil **("see a helical coil" in col.9, line 40)** and the outer layer comprises at least one polyurethane material **(col.9, lines 63-67)**.

As to claim 14, Giba discloses a catheter as in claim 13, wherein the at least one polyurethane material comprises at least two polyurethane materials for conferring varying levels of flexibility to the distal portion **(see "alloy" in col.9, lines 63-67)**.

As to claim 15, Giba discloses a catheter as in claim 13, wherein the at least one polyurethane material has an increasing amount of flexibility from a proximal end of the distal portion to a distal end of the distal portion **(col.9, lines 63-67, and col.10, lines 1-9)**.

As to claim 16, Giba discloses a catheter as in claim 1, wherein a pitch of the at least one coil is approximately 0.030 cm **(fig. 10 depicts that coil 130 is approximately 0.030 cm)**.

As to claim 17, Giba discloses a catheter as in claim 1, wherein the distal portion of the catheter body has a length of between about 1.2 cm and about 2.0 cm **(fig. 1 depicts that the catheter body 110 has a length of between about 1.2 cm and about 2.0 cm).**

As to claim 18, Giba discloses a catheter as in claim 17, wherein the at least one coil has a length of between about 1.6 cm and about 2.4 cm **(fig. 10 depicts that coil 130 has a length of between about 1.6 cm and about 2.4 cm).**

As to claim 19, Giba discloses a catheter as in claim 18, wherein the at least one coil extends through at least part of the distal portion of the catheter body and at least part of the proximal portion of the catheter body **(see fig.10)**.

As to claim 20, Giba discloses a catheter as in claim 19, wherein a distal end **(fig.1, 156)** of the proximal portion of the catheter body overlaps a proximal end of the distal portion of the catheter body.

As to claim 21, Giba discloses a catheter as in claim 18, wherein the length of the catheter body is between about 43 cm and about 50 cm **(fig.1 depicts that the catheter body 100 is between about 43 cm and about 50 cm).**

As to claim 22, Giba discloses a catheter as in claim 1, wherein an inner diameter of the proximal portion of the catheter body is smaller near the distal end of the catheter body than near

the proximal end **(see fig.1, were the catheter body tapes from proximal to distal, and the inner diameter of 102 is depicted as larger than the inner diameter of 110)**.

As to claim 26, Giba discloses a catheter for delivering a contraceptive device within a fallopian tube, the catheter comprising: an elongate tubular catheter body **(fig.1, 100)** having a proximal portion **(fig.1, 102)** adjacent a proximal end **(proximal end is toward the handle 102 and distal end is toward the elongated tube 110, see fig.1)**, a distal portion **(fig.1, 110)** adjacent a distal end **(distal end is toward the elongated tube 110, see fig.1)**, and at least one lumen **(fig.3 depicts that a lumen contains coil 130)**, wherein the distal portion is more flexible towards the distal end than towards the proximal end **(col.8, lines 15 and 16)**; and at least one coil **(figs.3 and 4, 130)** disposed along the catheter body nearer the distal end than the proximal end and encircling the lumen **(see figs. 3 and 4)**.

As to claim 27, Giba discloses a catheter for delivering a contraceptive device within a fallopian tube, the catheter comprising: an elongate tubular catheter body **(fig.1, 100)** having a proximal portion **(fig.1, 102)** adjacent a proximal end **(proximal end is toward the handle 102 and distal end is toward the elongated tube 110, see fig.1)**, a distal portion **(fig.1, 110)** of between about 1.2 cm and about 2.0 cm **(fig. 1 depicts that the distal portion 110 has a length of between about 1.2 cm and about 2.0 cm)** adjacent a distal end **(distal end is toward the elongated tube 110, see fig.1)**, and at least one lumen **(fig.3 depicts that a lumen contains coil 130)**, wherein the distal portion is more flexible towards the distal end than towards the proximal end **(see figs. 3 and 4)**; and at least one coil **(figs.3 and 4, 130)** disposed along the catheter body nearer the distal end than the proximal end and encircling the lumen **(see figs. 3 and 4, 130)**.

As to claim 28, discloses A system for delivering a contraceptive device within a fallopian tube, the system comprising: a catheter **(fig.1, 100)** comprising: an elongate tubular catheter body having a proximal portion adjacent a proximal end, a distal portion adjacent a distal end, and at least one lumen; and at least one coil disposed along the catheter body nearer the distal end than the proximal end and encircling the lumen; a contraceptive device releasably disposed at least partially within the lumen of the catheter near the distal portion; and a deployment member in detachable engagement with the contraceptive device for deploying the contraceptive device from the catheter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 28-35, and 37-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Khera et al. US 6,763,833 B1.

The applied reference has a common **assignee** with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the

inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

As to claim 28, Khera discloses a system for delivering a contraceptive device within a fallopian tube, the system comprising: a catheter **(fig. 1, 20,16)** comprising: an elongate tubular catheter body **(see fig.1)** having a proximal **(toward 30 in fig.1)** portion adjacent a proximal end **(fig.1, 32)**, a distal portion **(fig.1 depicts the distal end of the catheter)** adjacent a distal end, and at least one lumen **(fig.1 depicts that structure 18 is contained within a lumen)**; and at least one coil **(fig.3, 58)** disposed along the catheter body nearer the distal end than the proximal end and encircling the lumen **(see fig.3)**; a contraceptive device **(fig.1,12)** releasably disposed at least partially within the lumen of the catheter near the distal portion **(col.3, lines 60-65)**; and a deployment member **(fig.1, 18)** in detachable engagement with the contraceptive device for deploying the contraceptive device from the catheter **(col.9, lines 10-28)**.

As to claim 29, Khera discloses a system as in claim 28, wherein the distal portion of the catheter body is more flexible towards the distal end of the catheter body than towards the proximal end **(the distal portion is inherently more flexible due to the coil composition, see cols. 9 and 10)**.

As to claim 30, Khera discloses a system as in claim 29, wherein the distal portion of the catheter body comprises multiple layers **(figs. 1 and 3, reference objects 14, 50, and 58)**, and the at least one coil comprises one of the layers **(see fig.3)**.

As to claim 31, Khera discloses a system as in claim 30, wherein the multiple layers comprise: an inner layer **(see fig.3, 50)**; a middle layer **(fig.3, 58)**; and an outer layer **(fig.1, 14)**.

As to claim 32, Khera discloses a system as in claim 31, wherein the middle layer comprises the coil **(see fig.3)**.

As to claim 33, Khera discloses a system as in claim 32, wherein the coil comprises at least one material selected from the group consisting of Nitinol®, stainless steel, titanium and a polymer **(col.4, lines 49-60)**.

As to claim 34, Khera discloses a system as in claim 31, wherein the inner layer comprises at least one material selected from the group consisting of Teflon®, etched polytetraflouroethylene and a fluoropolymer **(col.4, lines 18-21)**.

As to claim 35, Khera discloses a system as in claim 31, wherein the outer layer comprises at least one polyurethane material **(col.4, lines 49-60)**.

As to claim 37, Khera discloses a system as in claim 29, wherein the distal portion comprises: a first segment **(fig.1B, 30)**; and at least a second segment **(fig.1. 20)** distal to the first segment, wherein the second segment is more flexible than the first segment **(the second segment deflects in to the uterus while the first segment stays outside of the uterus, thus the deflection nature makes the second segment more flexible than the first segment, see figs. 8 and 9).**

As to claim 38, Khera discloses a system as in claim 37, further comprising a third segment **(fig.1, 24)** distal to the second segment, wherein the third segment is more flexible than the second segment

As to claim 39, Khera discloses a system as in claim 38, wherein the distal portion comprises: an inner layer **(fig.3, 50)**; a middle layer **(fig.3, 58)**; and an outer layer **(fig.1, 14)**.

As to claim 40, Khera discloses a system as in claim 39, wherein the middle layer comprises the coil **(see fig.3)** and the outer layer comprises at least one polyurethane material **(col.4, lines 49-60)**.

As to claim 41, Khera discloses a system as in claim 40, wherein the at least one polyurethane material comprises at least two polyurethane materials for conferring varying levels of flexibility to the distal portion **(col.4, lines 49-60)**.

As to claim 42, Khera discloses a system as in claim 40, wherein the at least one polyurethane material has an increasing amount of flexibility from a proximal end of the distal portion to the distal end of the distal portion **(col.4, lines 49-60)**.

As to claim 43, Khera discloses a system as in claim 28, wherein the proximal portion of the catheter body includes at least one visualization marker near the distal portion for enhancing visualization of a proximal-most end of the distal portion **(col.4, lines 8-21)**.

As to claim 44, Khera discloses a system as in claim 43, wherein the visualization marker comprises at least one radiopaque material **(col.4, liens 8-21)**.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7,23-25, and 45-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giba et al. US 5,876,373.

As to claim 7, Giba lacks a catheter as in claim 8, wherein the polyurethane material comprises Carbothane. **However, a close review of Applicant's disclosure suggests that the Applicant has not stated why a particular polyurethane material is critical to the invention in terms of providing a specific function and solving a stated problem. Therefore, one of ordinary skill of art would consider the specific polyurethane material used in the claimed invention as a matter of design choice because the type of polyurethane used would not seem to affect how the catheter would function. Therefore, it would have been an obvious matter of design choice to modify Giba to obtain the invention as specified in claim 7.**

As to claim 23, Giba discloses a catheter as in claim 1, wherein the proximal portion of the catheter body comprises at least one polyether block amide. **However, polyether block amide is presented as an alternative material to polyurethane material (see page 6, paragraph 18 of Applicant's specification). Therefore, Giba's teaching of polyurethane material (col.9, lines 63-67 of Giba) is considered an alternative equivalent material to**

polyether block amide. Thus, Giba teaches an alternative catheter body material that is within the scope of the claimed limitation of "polyether block amide".

As to claim 24, Giba discloses a catheter as in claim 1, wherein the catheter body includes at least one visualization marker **(fig.10, 134)** near the distal portion for enhancing visualization of a proximal-most end of the distal portion **(col.10, lines 38-42), Giba however lacks the maker is located at the proximal portion of the catheter body. However, a close review of Applicant's disclosure suggests that the Applicant has not stated why a particular location of the marker is critical to the invention in terms of providing a specific function and solving a stated problem. Therefore, one of ordinary skill of art would consider location of the marker as a matter of design choice because where the marker is located would not affect how the marker would function. Therefore, it would have been an obvious matter of design choice to modify Giba to obtain the invention as specified in claim 24.**

As to claim 25, Giba teaches a catheter as in claim 24, wherein the visualization marker comprises at least one radiopaque material **(col.10, lines 38-42)**.

As to claims 45-54, Giba lacks the detailed method steps cited for claims 45-54. **However, Giba teaches structures that are required to perform the method steps cited in claims 45-54 (see rejection cited for claims 1-27). Therefore, it would have been obvious to one of ordinary skill in the art to obtain the method steps as specified in claims 45-54 through the use of Giba's catheter.**

Claims 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khera et al. US 6,763,833 B1.

As to claim 36, Khera discloses a system as in claim 35, wherein the polyurethane material comprises Carbothane. **However, a close review of Applicant's disclosure suggests that the Applicant has not stated why a particular polyurethane material is critical to the invention in terms of providing a specific function and solving a stated problem. Therefore, one of ordinary skill in the art would consider the specific polyurethane material used in the claimed invention as a matter of design choice because the type of polyurethane used would not seem to affect how the catheter would function. Therefore, it would have been an obvious matter of design choice to modify Khera to obtain the invention as specified in claim 36.**

Claim Objections

Claims 6,7,17,18,21,27,39,46, and 47 are objected to because of the following informalities:

Claims 6,7,46, and 47 are objected to because these claims recite limitation that is part of trademark name, i.e., Nitinol/Teflon. Applicant is requested to use a more generic terminology to address the trademark name(s) cited in claims 6,7,46, and 47.

Claim 39 is objected to because the recitation of "the distal portion" in line 1 lacks antecedent basis. For the examination purposes, claim 39 is considered depending from claim 28. Appropriate correction is required.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Benjamin (US 6,245,053 B1), and Nikolchev et al. (US 6,634,361 B1) are cited to teach catheter with coiled structure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

4/13/07

Shumaya B. Ali
Examiner
Art Unit 3771

JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700
4/13/07